REMARKS/ARGUMENTS

Claims 24 and 26-33 are pending in the application and are presented for examination. Claims 24 and 31 have been amended to more particularly point out and claim the subject matter Applicants regard as their invention. Reconsideration is respectfully requested.

The present methods are useful and very effective for the detection and diagnosis of diseases. In general, certain volatile marker gases characterize the detection or diagnosis of a disease state or medical condition. Using the present methods, it is possible to monitor the breath of an individual at time intervals and then compare the results of the response profiles to diagnose and monitor a medical condition.

I. FIRST REJECTION UNDER 35 § U.S.C. 103

Claims 24, 26, 27, 29 and 31 have been rejected as allegedly being obvious over U.S. Patent No. 5,971,937 ("Ekstrom") in view of U.S. Patent No. 6,282,441 ("Raymond *et al.*") The Examiner alleges that Ekstrom teaches the use of multiple sampling of breath samples and comparing the results to improve the reliability of the alcohol concentration measurements. The Examiner admits that Ekstrom does not teach or suggest storing any profile data. The Examiner alleges that Raymond *et al.* teach a data logger that stores the patient data. The Examiner alleges that the combined teaching makes the instant invention obvious. To the extent that the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

As set forth in M.P.E.P. § 2143:

> [t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure.

In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)

Applicants assert that a *prima facie* case of obviousness has not been established as there is no suggestion or motivation to modify the cited references.

There is no Suggestion or Motivation to Modify the References

Applicants state that there is simply no motivation or suggestion provided in the cited references to modify their teaching in the way the Office Action has contemplated. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

As amended, claim 26 of the present invention sets forth:

> A method for comparing the analyte profiles of mammalian breath samples for diagnosing and monitoring a medical condition, said method comprising:
> (a) contacting an array of sensors with a first sample of mammalian breath to identify analytes in said first sample; and
> (b) storing the results of the analysis of said first sample in a computer-readable format;
> (c) contacting an array of sensors with a second sample of mammalian breath to identify analytes in said second sample; and
> (d) comparing the results of said second sample with the stored results of the analysis of said first sample, thereby comparing the analyte profiles of mammalian breath samples, wherein the comparison of the analyte profiles are used to diagnose and monitor a medical condition.

The present methods are useful and very effective for the detection and diagnosis of diseases. In general, certain volatile marker gases characterize the detection or diagnosis of a disease state or medical condition. By using the present methods, it is possible to monitor a subject's breath for example, at time-1(t_1) and then monitor the subject's breath at time-2(t_2). By comparing the results of the response profiles, diagnosing and monitoring a medical condition is possible and facile.

Ekstrom teaches a method and apparatus for measuring a blood alcohol concentration. Ekstrom teaches at column 9, lines 23-52:

> In addition to the utilization of the above-described carbon dioxide measuring and the threshold values defined therefor, **the reliability of alcohol measuring** can be improved by one or more of the following procedures. The plateau sections F3 occurring in the exhalation carbon dioxide concentration and alcohol concentration can be detected by measuring either carbon dioxide concentration Rb or alcohol concentration Ra over an exhalation time Tm, either continuously or several times. Thus, the plateau section F3 is **verifiable by comparing two or more successive measured values** and differences ΔRa and/or ΔRb therebetween. In case ΔRa and/or ΔRb over a given time difference ΔT or volume difference ΔV is smaller than a predetermined value, it can be concluded that exhalation has reached the plateau section F3 and in this respect a reliable alcohol measurement could be effected. As another alternative, it is possible to measure an exhalation time Tx or an exhalation volume Vx and to compare these with sufficiently high but realistic maximum values Tm and Vm provided by normal exhalation and, if the former are to a sufficient degree lower than these maximum values Tm and Vm, it can be **concluded that a subject has not taken a sufficiently clear breath from the deep lungs**. The output of alcohol content is produced by using either the average or weighted average of alcohol concentration Ra calculated over the duration or some portion of the duration of the plateau section F3 or a value picked up at some point in the plateau section or the highest detected alcohol concentration value, which in most cases is the value Ra near the end of exhalation. [Emphasis added].

It is clear from the above passage that the any multiple or successive measurements are for **verifying the reliability** of alcohol measuring. Thus, the purpose of multiple measurements is for making the measurements more reliable.

In fact, the Examiner appears to be in agreement with the purpose of any multiple measurement readings by Ekstrom. The Examiner states on page 6, of the current Office Action:

> Ekstrom recites the use of multiple measurements and then comparing them to ***insure an accurate and reliable measurement*** of the analyte based on the readings obtained over time.

In the present invention, amended claim 26 clearly sets forth that the results of the second sample are compared with the stored results of the analysis of the first sample for ***diagnosing and monitoring*** a medical condition. As discussed on page 11, bridging to the top of page 12, of the present application as filed, "the methods and apparatus of the present invention can advantageously be used to detect volatile marker gases and compounds indicative of medical conditions, disease processes, infections, illness and well-being. Using these marker gases and compounds, clinicians can use the diagnostic instruments and methods of the present invention to make diagnoses and formulate appropriate treatments."

Raymond *et al.* do not supply the deficiencies of the primary reference. Raymond *et al.* teach a health monitoring system that compiles a chronological health history of the patient using a multiparametric monitor that periodically and automatically measures and records physiological data from sensors in contact with the patient's body. There is absolutely no teaching or suggestion of profiling mammalian ***breath samples*** for diagnosing and monitoring a medical condition.

As the Examiner is aware, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

Ekstrom uses multiple or successive measurements to ensure ***reliability*** of the data. Raymond *et al.* do not teach or suggest profiling mammalian ***breath samples.*** As such, a *prima facie* case of obviousness has not been established. Therefore, Applicants respectfully request that the rejection be withdrawn.

II. SECOND REJECTION UNDER 35 § U.S.C. 103

The Examiner has rejected claim 30 under U.S.C. § 103(a) as allegedly being obvious over Ekstrom and Raymond *et al.*, and further in view of Lemelson. To the extent that the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

As discussed above, Ekstrom teaches multiple samples or successive measurement values for the sole purpose of **verifying the reliability** of alcohol measuring.

Raymond *et al.* do not teach or suggest profiling mammalian **breath samples**.

The tertiary reference of Lemelson teaches a method for analyzing body fluids that may be used for testing the breath of humans. However, Lemelson does not teach or suggest storing the analysis results of a first breath sample in a computer-readable format and comparing this analysis results with a second breath sample for diagnosis and monitoring a disease as is presently taught and claimed. In fact, Lemelson discusses simply comparing the breath sample analysis "with a set point" which can be "determined by a simple calculation or table look-up using data inputted by the user...." (please see col. 9, lines 19-21). Thus, combination of the teachings of Ekstrom and Lemelson would results in analyzing the breath samples to a set data point that is calculated or is inputted by the operator.

In contrast, methods of the present invention comprise comparing the analysis results of a first breath sample with a second breath sample for diagnosing and monitoring a medical condition. The methods of the present invention can advantageously be used to detect volatile marker gases and compounds indicative of medical conditions, disease processes, infections, illness and well-being. Using these marker gases and compounds, clinicians can use the diagnostic methods of the present invention to make diagnoses and formulate appropriate treatments.

As amended, claim 30 sets forth:

> A method for comparing the analyte profiles of mammalian breath samples for diagnosing and monitoring a medical condition, said method comprising:
> (a) contacting an array of sensors with first sample of mammalian breath;
>
> (b) detecting a first set of responses from said array of sensors, wherein said set of responses is a first sensor array response profile;
> (c) analyzing said first sensor array response profile to identify analytes in said first sample;
> (d) storing said first sensor array response profile and the results of the analysis;
> (e) contacting an array of sensors with a second sample of mammalian breath;

(f) detecting a second set of responses from said array of sensors, wherein said set of responses is a second sensor array response profile;
(g) analyzing said second sensor array response profile to identify analytes in said second sample; and
(h) comparing the results of the analysis of said first and second breath samples, wherein the comparison of the results are used to diagnose and monitor a medical condition.

The combination of cited references simply do not teach or suggest comparing the results of the analysis of the first and second breath samples, wherein the comparison of the results are used to diagnose and monitor a medical condition as is presently taught and claimed. Accordingly, Applicants respectfully request that the rejection of claim 30 under 35 U.S.C. § 103(a) be withdrawn.

III. THIRD REJECTION UNDER 35 § U.S.C. 103

The Examiner has rejected claims 24, 28 and 31-33 under 35 U.S.C. § 103(a) as allegedly being obvious over Rounbehler *et al.* in view of Ekstrom and further in view of Raymond *et al.* To the extent that the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Applicants assert that the combined references do not teach or suggest the present invention. Again, by using the present methods, it is possible to monitor an individual's breath for example, at time-1(t_1) and then monitor the subject's breath at time-2(t_2). By comparing the results of the response profiles, diagnosing and monitoring a medical condition is possible and facile.

The cited references do not teach or suggest comparing the results of the analyte profiles from two samples, wherein the comparison of the analyte profiles are used to diagnose and monitor a medical condition.

Rounbehler *et al.* teach in Figure 7, that a patient provides a single sample for analysis. The sample is analyzed via a GC type of detector. Rounbehler *et al.* teach at the bottom of column 6, bridging to column 7:

> Referring to FIG. 7, a flow chart illustrates how a vapor sample may be analyzed on the system described above. **In the first step 80, the patient exhales into inhaler/exhaler 20 thereby providing a breath sample.** In step 82, the sample in vapor form is drawn into the GC sample loop 62. Valve 54 is positioned to cause flow from the sample inlet 48 through sample loop 62 and out sample outlet 50. In the next step 84, valve 54 is actuated to direct carrier gas from inlet 64 through sample loop 62 to sweep the sample to cold spot 310, where the sample becomes concentrated. As indicated in step 86, cold spot 310 is heated which causes the sample to be released from cold spot 310 and directed to column 44. In the next step 88, the components of the vapor sample are separated in the fast GC column. [Emphasis added].

There is no teaching or suggestion of diagnosing or monitoring a medical condition using multiple breath samples. In the present invention, the second sample is compared with the stored results of the analysis of the first sample for ***diagnosing and monitoring*** a medical condition. As discussed on page 11, bridging to the top of page 12, "the methods and apparatus of the present invention can advantageously be used to detect volatile marker gases and compounds indicative of medical conditions, disease processes, infections, illness and well-being. Using these marker gases and compounds, clinicians can use the diagnostic instruments and methods of the present invention to make diagnoses and formulate appropriate treatments."

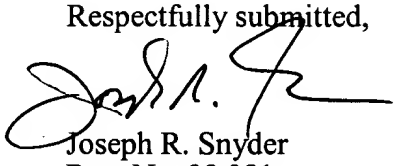
Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

IV. CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. Applicants urge the Examiner to send this application to issue.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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